

## State Medical Facilities Plan

Chapter 230.  
State Medical Facilities Plan.PART I.  
Definitions and General Information

## 12 VAC 5-230-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Accessibility" means the ability of a population or segment of the population to obtain ~~appropriate, available services. This ability is determined by economic, temporal, locational, architectural, cultural, psychological, organizational and informational factors which may by barriers or facilitators to obtaining services.~~

~~"Acceptability" means to the level of satisfaction expressed by consumers with the availability, accessibility, cost, quality, continuity and degree of courtesy and consideration afforded them by the health care system.~~

"Acute psychiatric services" means hospital-based inpatient psychiatric services provided in distinct inpatient units in general hospitals or freestanding psychiatric hospitals.

"Acute substance abuse disorder treatment services" means short term hospital-based inpatient treatment services with access to the resources of: (i) a general hospital, (ii) a psychiatric unit in a general hospital, or (iii) an acute care addiction treatment unit in a general hospital licensed by the Department of health, or (iii) a chemical dependency specialty hospital with acute care medical and nursing staff and life support equipment licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

"Applicant" means any individual, corporation, partnership, association, trust, or other legal entity, whether governmental or private, submitting an application for a Certificate of Public Need.

"Availability" means the quantity and types of health services that can be produced in a certain area given the supply of resources to produce those services.

"Cardiac catheterization" means a procedure where a flexible tube is inserted into the patient through an extremity blood vessel and advanced under fluoroscopic guidance into the heart chambers to perform: (i) a hemodynamic, electrophysiologic or angiographic examination of the left or right heart chamber or the coronary arteries, (ii) aortic root injections to examine the degree of aortic root regurgitation or deformity of the aortic valve, or (iii) angiographic procedures to evaluate the coronary arteries. Therapeutic intervention in a coronary artery may also be performed using cardiac catheterization. Cardiac catheterization does not include a

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simple right heart catheterization for monitoring purposes as might be performed in an electrophysiology laboratory, pulmonary angiography as an isolated procedure, or cardiac pacing through a right electrode catheter.

“Certificate of Public Need” or “COPN” means the orderly administrative process used to make medical care facilities and services needs decisions.

“Charges” means all expenses incurred by the provider in the production and delivery of health services.

“Commissioner” means the State Health Commissioner.

“Competing applications” means applications for the same or similar services and facilities that are proposed for the same planning district and are in the same batch review cycle.

“Computed tomography” or “CT” means a noninvasive diagnostic technology that uses computer analysis of a series of cross-sectional scans made along a single axis of a bodily structure or tissue to construct a three-dimensional image of that structure.

“Condition” means the agreed upon qualifications placed on a project by the commissioner when granting a Certificate of Public Need. Such conditions shall direct an applicant to provide a level of care to indigents, accept patients requiring specialized needs, or facilitate the development and operation of primary care services in designated medically underserved areas of the applicant’s service area.

“Continuing care retirement community” or “CCRC” means a retirement community consistent with the requirements of Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia. CCRCs can have nursing home services available on-site or at licensed facilities off-site.

“Continuity of care” means the extent of effective coordination of services provided to individuals and the community over time, within and among health care settings.

“Costs” means all expenses incurred in the production and delivery of health services.

“Department” means the Virginia Department of Health.

“General inpatient hospital beds” means beds located in the following units or categories:

1. Medical/surgical units available for the care and treatment of adults not requiring specialized services; and
2. Pediatric units that are maintained and operated as a distinct unit for use by patients younger than 21. Newborn cribs and bassinets are excluded from this definition.

“Health planning region” means a contiguous geographic area of the Commonwealth as designated by the department with a population base of at least 500,000 persons, characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary

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care, and congruence with planning districts.

"Hospital" means a medical care facility licensed as a general, community, or special hospital licensed by the Department of Health or a psychiatric hospital licensed by the Department of Mental Health, Mental Retardation, and Substance Abuse Services.

"Hospital-based" means a service operating physically within, connected to a hospital, or on the hospital campus, and legally associated with a hospital.

"Indigent or uninsured" means persons eligible to receive reduced rate or uncompensated care at or below Income Level E as defined in 12 VAC 5-200-10 of the Virginia Administrative Code.

"Inpatient beds" means accommodations in a medical care facility with continuous support services, such as food, laundry, housekeeping, and staff to provide health or health-related services to patients who generally remain in the facility in excess of 24 hours. Such accommodations are known by various nomenclatures including but not limited to: nursing facility, intensive care, minimal or self care, isolation, hospice, observation beds equipped and staffed for overnight use, obstetric, medical/surgical, psychiatric, substance abuse disorder, medical rehabilitation, and pediatric. Bassinets and incubators and beds in labor and birthing rooms, emergency rooms, preparation or anesthesia induction rooms, diagnostic or treatment procedure rooms, or on-call staff rooms are excluded from this definition.

"Intensive care beds" means acute care beds located in the following units or categories:

1. General intensive care units are those units where patients are concentrated by reason of serious illness or injury regardless of diagnosis. Special lifesaving techniques and equipment are immediately available and patients are under continuous observation by nursing staff;
2. Cardiac care units are units staffed and equipped solely for the intensive care of cardiac patients; and
3. Specialized intensive care units are any units with specialized staff and equipment for the purpose of providing care to seriously ill or injured patients for selected categories of diagnoses, including units established for burn care, trauma care, neurological care, pediatric care, and cardiac surgery recovery. This category of beds does not include neonatal intensive care units.

"Intermediate care substance abuse disorder treatment services" means long term hospital-based inpatient treatment services that provide structured programs of assessment, counseling, vocational rehabilitation, and social rehabilitation.

"Lithotripsy" means a noninvasive therapeutic procedure of crushing kidney, renal and biliary stones using shock waves. Lithotripsy can also be used to fragment matter such as calcifications or bone and to relieve the pain associated with tendonitis.

"Magnetic resonance imaging" or "MRI" means a non-invasive diagnostic technology using a nuclear spectrometer to produce electronic images of specific atoms and molecular structures in solids, especially human cells, tissues and organs.

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"Minimum survival rates" means the lowest percentage of those receiving organ transplants who survive at least one year or for such other period of time as specified by the United Network for Organ Sharing.

"MRI relevant patients" means the sum of: 0.55 times the number of patients with a principal diagnosis involving neoplasms (ICD-9-CM codes 140-239); 0.70 times the number of patients with a principal diagnosis involving diseases of the central nervous system (ICD-9-CM codes 320-349); 0.40 times the number of patients with a principal diagnosis involving cerebrovascular disease (ICD-9-CM codes 430-438); 0.40 times the number of patients with a principal diagnosis involving chronic renal failure (ICD-9-CM code 585); 0.19 times the number of patients with a principal diagnosis involving dorsopathies (ICD-9-CM codes 720-724); 0.40 times the number of patients with a principal diagnosis involving diseases of the prostate (ICD-9-CM codes 600-602); and 0.40 times the number of patients with a principal diagnosis involving inflammatory disease of the ovary, fallopian tube, pelvic cellular tissue or peritoneum (ICD-9-CM code 614). The applicant shall have discharged all patients in these categories during the most recent 12-month reporting period.

"Neonatal special care" means care for infants in one or more of the three service levels designated in 12 VAC 5-410-440 D 2 of the "Rules and Regulations for the Licensure of Hospitals, i.e., intermediate level newborn services, specialty level newborn services, or subspecialty level newborn services.

"Network" means a group of medical care facilities, including hospitals, or health care systems, legally or operationally associated with one or more hospitals in a planning region.

"Nursing facility" means those facilities or components thereof licensed to provide long-term nursing care.

"Nursing facility beds" means inpatient beds which are located in distinct units of general hospitals that are licensed as long-term care units by the department. Beds in these long-term units are not included in the calculations of inpatient bed need.

"Obstetrical services" means the distinct organized program, equipment and care related to pregnancy and the delivery of newborns in inpatient facilities.

"Off-site replacement" means the relocation of existing beds or services from an existing medical care facility site to another location within the same planning district.

"Open heart surgery" means a set of surgical procedures using a heart-lung bypass machine or pump to perform extracorporeal circulation and oxygenation during surgery. This technique is used when the heart must be slowed down to correct congenital and acquired cardiac and coronary artery disease. The use of the pump during the procedure distinguishes "open heart" from "closed heart" surgery.

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"Operating room" means a room, meeting the requirements of 12 VAC 5-410-820, in a licensed general or outpatient surgical hospital used solely or principally for the provision of surgical procedures, excluding endoscopic and cystoscopic procedures.

"Operating room use" means the amount of time a patient occupies an operating room, plus the estimated or actual room preparation and cleanup time.

"Operating room visit" means one session in one operating room in a licensed general hospital or outpatient surgical hospital, which may involve several procedures. Operating room visit may be used interchangeably with "operation" or "case."

"Outpatient " means services provided to individuals who are not expected to require overnight hospitalization but who require treatment in a medical care facility exceeding the normal capability found in a physician's office. For the purposes of this chapter, outpatient services refers only to surgical services provided in operating rooms in licensed general hospitals or licensed outpatient surgical hospitals, and does not include surgical services provided in outpatient departments, emergency rooms, or treatment rooms of hospitals, or physicians' offices.

"Pediatric cardiac catheterization" means the cardiac catheterization of patients less than 21 years of age.

"Perinatal services" means those resources and capabilities that all hospitals offering general level newborn services as described in 12 VAC 5-410-440.D.2.a (1) of the "Rules and Regulations for the Licensure of Hospitals" must provide routinely to newborns.

"Physician" means a person licensed by the Board of Medicine to practice medicine or osteopathy in Virginia.

"Planning district" means a contiguous area within the boundaries established by the Virginia Department of Housing and Community Development or its successor.

"Planning horizon year" means the particular year for which bed needs are projected.

"Population" means the census figures shown in the most current series of projections published by the Virginia Employment Commission.

"Positron emission tomography" or "PET" means a non-invasive diagnostic using the computer-generated image of local metabolic and physiological functions in tissues produced through the detection of gamma rays emitted when introduced radio-nuclids decay and release positrons. A PET system includes two major elements: (i) a cyclotron that produces radio-pharmaceuticals and (ii) a scanner that includes a data acquisition system and a computer.

~~"Quality of care" means to the degree to which services provided are properly matched to the needs of the population, are technically correct, and achieve beneficial impact. Quality of care~~

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~~can include consideration of the appropriateness of physical resources, the process of producing and delivering services, and the outcomes of services on health status, the environment, and/or behavior.~~

"Radiation therapy" means the treatment of disease with radiation, especially by selective irradiation with x-rays or other ionizing radiation and by ingestion of radioisotopes.

"Relevant reporting period" means the most recent 12-month period, prior to the beginning of the applicable batch review cycle, for which data is available from the Virginia Employment Commission, Virginia Health Information, or other source identified by the department.

"Rural" means territory, population, and housing units that are classified as "rural" by the Bureau of the Census of the United States Department of Commerce, Economic and Statistics Administration.

"State medical facilities plan" or "SMFP" means the planning document adopted by the Board of Health that includes, but is not limited to, (i) methodologies for projecting need for medical facility beds and services; (ii) statistical information on the availability of medical facility beds and services; and (iii) procedures, criteria and standards for the review of applications for projects for medical care facilities and services.

"Stereotactic radiosurgery" means a noninvasive therapeutic procedure for precisely locating points within the body using an external, 3-dimensional frame of reference. A stereotactic instrument is attached to the body and used to localize precisely an area in the body by means of coordinates related to anatomical structures. An example of a stereotactic radiosurgery instrument is a Gamma Knife® unit.

"Study" or "scan" means the gathering of data during a single patient visit from which one or more images may be constructed for the purpose of reaching a definitive clinical diagnosis.

"Substance abuse disorder treatment services" means services provided to individuals for the prevention, diagnosis, treatment, or palliation of chemical dependency, which may include attendant medical and psychiatric complications of chemical dependency.

"The Center" means The Center for Quality Health Care Services and Consumer Protection.

"Use rate" means the rate at which an age cohort or the population uses medical facilities and services. The rates are determined from periodic patient origin surveys conducted for the department by the regional health planning agencies, or other health statistical reports authorized by Chapter 7.2 (§ 32.1-276.2 et seq.) of Title 32.1 of the Code of Virginia.

12 VAC 5-230-20. ~~Preface.~~ Responsibility of the department.

~~Virginia's Certificate of Public Need law defines the State Medical Facilities Plan as the "planning document adopted by the Board of Health which shall include, but not be limited to,~~

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~~(i) methodologies for projecting need for medical facility beds and services; (ii) statistical information on the availability of medical facility beds and services; and (iii) procedures, criteria and standards for the review of applications for projects for medical care facilities and services." (. 32.1-102.1 of the Code of Virginia.)~~

~~Section 32.1-102.3 of the Code of Virginia states that, "Any decision to issue or approve the issuance of a certificate (of public need) shall be consistent with the most recent applicable provisions of the State Health Plan and the State Medical Facilities Plan; provided, however, if the commissioner finds, upon presentation of appropriate evidence, that the provisions of either such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan."~~

~~Subsection B of . 32.1-102.3 of the Code of Virginia requires the commissioner to consider "the relationship" of a project "to the applicable health plans of the board" in "determining whether a public need for a project has been demonstrated."~~

~~This State Medical Facilities Plan is a comprehensive revision of the criteria and standards for COPN-reviewable medical care facilities and services contained in the Virginia State Health Plan established from 1982 through 1987, and the Virginia State Medical Facilities Plan, last updated in July, 1988. This Plan supersedes the State Health Plan 1980-1984 and all subsequent amendments thereto save those governing facilities or services not presently addressed in this Plan.~~

~~A. Virginia's Certificate of Public Need law defines the State Medical Facilities Plan as the "planning document adopted by the Board of Health which shall include, but not be limited to, (i) methodologies for projecting need for medical facility beds and services; (ii) statistical information on the availability of medical facility beds and services; and (iii) procedures, criteria and standards for the review of applications for projects for medical care facilities and services." (. 32.1-102.1 of the Code of Virginia.)~~

A. Sections 32.1-102.1 and 32.1-102.3 of the Code of Virginia requires the Board of Health to adopt a planning document for review of COPN applications and that decisions to issue a COPN shall be consistent with the most recent provisions of the State Medical Facilities Plan.

B. The commissioner is the designated decision maker in the process of determining public need.

C. The Center is a unit of the department responsible for administering the COPN program under the direction of the commissioner.

D. The regional health planning agencies assist the department in determining whether a certificate should be granted.

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E. The Center's COPN staff is available to answer questions and provide technical assistance throughout the application process.

F. In developing or revising standards for the COPN program, the board adheres to the requirements of the Administrative Process Act and the public participation process. The department, acting for the board, solicits input from applicants, applicant representatives, industry associations, and the general public in the development or revision of these criteria through informal and formal comment periods and may hold public hearings, as appropriate.

G. If, upon presentation of appropriate evidence, the commissioner finds that the provisions of this chapter are not relevant to a rural locality's needs, or are inaccurate, outdated, inadequate or otherwise inapplicable, he may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to this chapter.

12 VAC 5-230-30. Guiding principles in certificate of public need.

The following general principles ~~will be used in guiding the implementation of Virginia's Medical Care Facilities Certificate of Public Need (COPN) Program and have served~~ serve as the basis for the development of the review criteria and standards for specific medical care facilities and services contained in this document:

1. The COPN program will give preference to requests that encourage medical care facility and service development approaches that ~~document improvement in~~ improve the cost-effectiveness of health care delivery. Providers should strive to develop new facilities and equipment and use already available facilities and equipment to deliver needed services at the same or higher levels of quality and effectiveness, as demonstrated in patient outcomes, at lower costs.
2. The COPN program ~~will seek~~ seeks to achieve a balance between ~~appropriate the~~ the levels of availability and access to medical care facilities and services for all ~~the citizens of Virginia of Virginia's citizens, regardless of their ability to pay,~~ and the need to constrain excessive facility and service capacity.
3. The COPN program ~~will seek~~ seeks to achieve economies of scale in development and operation, ~~and optimal quality of care,~~ through establishing limits on the development of specialized medical care facilities and services on a statewide, regional, or planning district basis.
4. The COPN program ~~will give preference to~~ seeks to promote the development and maintenance of needed services that are accessible to every person who can benefit from the services regardless of their ability to pay.
5. ~~The COPN program promotes the elimination of excessive facility and service capacity.~~ The COPN program ~~will promote~~ promotes the elimination and conversion of excess facility and service capacity to meet identified needs. ~~The COPN program will not facilitate the survival of medical care facilities and services that are rendered superfluous by changes in health care delivery and financing.~~

12 VAC 5-230-40. General application filing criteria.

A. In addition to meeting the requirements of the State Medical Facilities Plan, applicants

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for a Certificate of Public Need shall provide documentation that their proposal also addresses the applicable twenty considerations listed in §32.1-102.3 of the Code of Virginia.

B. Facilities and services shall be provided in locations that meet established zoning regulations, as applicable.

C. The department shall consider an application complete when all requested information, and the application fee, is submitted on the form required. If the department finds the application incomplete, the applicant will be notified in writing and the application may be held for possible review in the next available applicable batch review cycle.

12 VAC 5-230-50. Project costs.

The capital development and operating costs for providing services should be comparable to similar services in the health planning region.

12 VAC 5-230-60. Preferences.

In the review of competing applications, preference will be given to applicants:

1. Who have an established performance record in completing projects on time and within the authorized capital costs;

2. Whose proposals have lower direct construction costs and cost of equipment than their competitors and can demonstrate that their cost estimates are credible;

3. Who can demonstrate a commitment to facilitate the transport of patients residing in rural areas or medically underserved areas of urban localities to needed services, directly or through coordinated efforts with other organizations;

4. Who can demonstrate a consistent compliance with state licensure and federal certification regulations and a consistent history of few documented complaints, where applicable; or

5. Who can demonstrate a commitment to enhancing financial accessibility to services through the provision of documented charity care, exclusive of bad debts and disallowances from payers, and services to Medicaid beneficiaries.

12 VAC 5-230-70. Emerging technologies.

Inasmuch as the SMFP cannot contemplate all possible future applications and advances in the regulated technologies, these future applications and technological advances will be evaluated based on emerging national trends and evidence in the peer review literature. Until such time as the SMFP can be updated to reflect changes, emerging technologies should be registered with the Center following 12 VAC 5-220-110 of the Virginia Administrative Code.

12 VAC 5-230-80. Institutional need.

Notwithstanding any other provisions of this chapter, consideration will be given to the

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expansion of services at existing medical care facilities in planning districts with an excess supply of such services when the proposed expansion can be justified on the basis of facility-specific utilization or geographic remoteness. If a facility with an institutional need is part of a network, the under-utilized services at other facilities within the network should be relocated to the facility within the planning district with the institutional need when possible.

12 VAC 5-230-90. Compliance with the terms of a condition.

A. The commissioner may condition the approval of a COPN to provide care to Virginia's indigent population, patients with specialized needs, or the medically underserved.

B. The applicant shall actively seek to provide opportunities to offer the conditioned service directly to indigent or uninsured persons at a reduced rate or free of charge to patients with specialized needs, or by the facilitation of primary care services in designated medically underserved areas.

C. If the direct provision of the conditioned services does not fulfill the terms of the condition, the Center may determine the applicant to be in compliance with the terms of the condition when:

1. The applicant is part of a facility or provider network and the facility or provider network has provided reduced rate or uncompensated care at or above the regional standard; or
2. The applicant provides direct financial support for community based health care services at a value equal to or greater than the difference between the terms of the condition and the amount of direct care provided.

Such direct financial support shall be in addition to, and not a substitute for, other charitable giving chosen by the applicant.

D. Acceptable proof for direct financial support is a signed receipt indicating the number or amount of services or other support provided and dollar value of that service or support. Applicants providing direct financial support for community based health care services should render that support through one of the following organizations:

1. The Virginia Association of Free Clinics;
2. The Virginia Health Care Foundation; or
3. The Virginia Primary Care Association.

E. Applicants shall demonstrate compliance with the terms of a condition for the previous 12 month period. The written condition report shall be certified or affirmed by the applicants and filed with The Center. Such report shall include, but is not limited to, the:

1. Facility or service name and address;
2. Certificate number;
3. Facility or service gross patient revenues;
4. Dollar value of the charity care provided, excluding bad debts and disallowances from

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payers; and

5. Number of individuals served by the direct provision of care or a receipt from one of the allowable organizations listed in subsection D.

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PART II.  
DIAGNOSTIC IMAGING SERVICES.

Article 1.  
Criteria and Standards for Computed Tomography.

12 VAC 5-230-100. Accessibility.

CT services should be within 30 minutes driving time one way, under normal conditions, of 95% of the population of the planning district.

12 VAC 5-230-110. Need for new service.

A. No CT service should be approved at a location that is within 30 minutes driving time one way of:

1. A service that is not yet operational; or
2. An existing CT unit has performed fewer than 3,000 scans during the relevant reporting period.

B. No new CT service or network shall be approved unless all existing CT services or networks in the planning district performed an average of 4,500 CT scans per machine during the relevant reporting period.

C. Consideration may be given to new CT services proposed for sites located beyond 30 minutes driving time one way of existing facilities that do not meet the 4,500 scans per machine criterion if the proposed sites are in rural areas.

12 VAC 5-230-120. Expansion of existing service.

Proposals to increase the number of CT scanners in an existing CT service or network may be approved only if the existing service or network performed an average of 3,000 CT scans for the relevant reporting period.

12 VAC 5-230-130. Staffing.

Providers of CT services should be under the direct, supervision of one or more board certified diagnostic radiologists

12 VAC 5-230-140. Space.

Applicants shall provide documentation that:

1. An suitable environment will be provided for the proposed CT services, including protection against known hazards; and

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2. Space will be provided for patient waiting, patient preparation, staff and patient bathrooms, staff activities, storage of records and supplies, and other space necessary to accommodate the needs of handicapped persons.

Article 2.Criteria and Standards for Magnetic Resonance Imaging.12 VAC 5-230-150. Accessibility.

MRI services should be within 30 minutes driving time one way, under normal conditions, of 95% of the population of the planning district.

12 VAC 5-230-160. Need for new service.

A. No new MRI services shall be approved unless all existing services in the planning district performed an average of 4,000 scans per machine during the relevant reporting period.

B. Consideration may be given to new MRI services proposed for sites located beyond 30 minutes driving time one way of existing facilities that do not meet the 4,000 scans per machine criterion if the proposed sites are in rural areas.

12 VAC 5-230-170. Expansion of services.

Proposals to expand existing MRI services through the addition of a new scanning unit may be approved if the existing service performed at least 4,000 scans per existing unit during the relevant reporting period.

12 VAC 5-230-180. Staffing.

MRI machines should be under the direct, on-site supervision of one or more board certified diagnostic radiologists.

12 VAC 5-230-190. Space.

Applicants should provide documentation that:

1. An suitable environment will be provided for the proposed MRI services, including shielding and protection against known hazards; and

2. Space will be provided for patient waiting, patient preparation, staff and patient bathrooms, staff activities, storage of records and supplies, and other space necessary to accommodate the needs of handicapped persons.

Article 3.Magnetic Source Imaging.12 VAC 5-230-200. Policy for the development of MSI services.

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Because Magnetic Source Imaging (MSI) scanning systems are still in the clinical research stage of development with no third party payment available for clinical applications, and because it is uncertain as to how rapidly this technology will reach a point where it is shown to be clinically suitable for widespread use and distribution on a cost-effective basis, the entry and development of this technology in Virginia should initially occur at, or in affiliation with, the academic medical centers in the state.

Article 4.  
Positron Emission Tomography.

12 VAC 5-230-210. Accessibility.

The service area for each proposed PET service shall be an entire planning district.

12 VAC 5-230-220. Need for service.

A Whether the applicant is a consortium of hospitals, a hospital network, or a single general hospital, at least 850 new PET appropriate cases should have been diagnosed in the planning district.

B. If the applicant is a general hospital, the facility shall provide radiation therapy services and specific ancillary services suitable for the equipment, and have reported at least 500 new courses of treatment or at least 8,000 treatment visits in the most recent reporting period.

C. If the applicant is a consortium of general hospitals or a hospital network, at least one of the consortium or network members shall provide radiation therapy services and specific ancillary services suitable for the equipment, and have reported at least 500 new PET appropriate patients.

D. Future applications of PET equipment shall be evaluated based on review of national literature.

12 VAC 5-230-230. Additional scanners.

No additional PET scanners shall be added in a planning district unless the applicant can demonstrate that the utilization of the existing PET service was at least 1,200 PET scans for a fixed site unit and that the proposed new or expanded service would not reduce the utilization of existing services below 850 PET scans for a fixed site unit. The applicant shall also provide documentation that the project complies with 12 VAC 5-230-240.

12 VAC 5-230-240. Staffing.

PET services should be under the direction of a physician who is board certified radiologist. Such physician shall be a designated authorized user of isotopes used for PET by the

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Nuclear Regulatory Commission or licensed by the Office of Radiologic Health of the Virginia Department of Health, as applicable.

Article 5.

Non-Cardiac Nuclear Imaging Criteria and Standards.

12 VAC 5-230-250. Accessibility.

Non-cardiac nuclear imaging services should be available within 30 minutes driving time one way, under normal driving conditions, of 95% of the population of the planning district.

12 VAC 5-230-260. Introduction of a service.

Any applicant proposing to establish a medical care facility for the provision of non-cardiac nuclear imaging, or introducing nuclear imaging as a new service at an existing medical care facility, shall provide documentation that the service can achieve a minimum utilization level of: i) 650 scans in the first 12 months of operation, ii) 1,000 scans in the second 12 months of services, and iii) 1,250 scans in the second 12 months of operation.

12 VAC 5-230-270. Staffing.

The proposed new or expanded nuclear imaging service shall be under the direction of a board certified physician. Such physicians shall be a designated authorized user of isotopes licensed by the Nuclear Regulatory Commission or the Office of Radiologic Health of the Virginia Department of Health, as applicable.

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PART. III.  
RADIATION THERAPY SERVICES.

Article 1.  
Radiation Therapy Services.

12 VAC 5-230-280. Accessibility.

Radiation therapy services should be available within 60 minutes driving time one way, under normal conditions, for 95% of the population of the planning district.

12 VAC 5-230-290. Availability.

A. No new radiation therapy service shall be approved unless: (i) existing radiation therapy machines located in the planning district were used for at least 320 cancer cases and at least 8,000 treatment visits for the relevant reporting period; and (ii) it can be reasonably projected that the new service will perform at least 6,000 procedures by the third year of operation without reducing the utilization of existing radiation therapy machines within 60 minutes drive time one way, under normal conditions, such that less than 8,000 procedures will be performed by an existing machine.

B. The number of radiation therapy machines needed in a primary service area will be determined as follows:

$$\frac{\text{Population} \times \text{Cancer Incidence Rate} \times 60\%}{320}$$

where:

1. The population is projected to be at least 75,000 people three years from the current year as reported in the most current projections of the Virginia Employment Commission;
2. The "Cancer incidence rate" is based data from the Statewide Cancer Registry;
3. 60% is the estimated number of new cancer cases in a planning district that are treatable with radiation therapy; and
4. 320 is 100% utilization of a radiation therapy machine based upon an anticipated average of 25 treatment visits per case.

C. Consideration will be given to the approval of new radiation therapy services located at a general hospital at least 60 minutes driving time one way, under normal conditions, from any site that radiation therapy services are available if the applicant can demonstrate that the proposed new services will perform at least 4,500 treatment procedures annually by the second year of operation, without reducing the utilization of existing machines located within 60 minutes driving time one way, under normal conditions, from the proposed new service location.

D. Proposals for the expansion of radiation therapy services should not be approved unless all existing radiation therapy machines operated by the applicant in the planning district

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have performed at least 8,000 procedures for the relevant reporting period.

12 VAC 5-230-300. Statewide Cancer Registry.

Facilities with radiation therapy services shall participate in the Statewide Cancer Registry as required by Article 9 (32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

12 VAC 5-230-310. Staffing.

Radiation therapy services shall be under the direction of a physician board certified in radiation oncology.

12 VAC 5-230-320. Equipment, patient care; support services.

In addition to the radiation therapy machine, the service should have direct access to:

1. Simulation equipment capable of precisely producing the geometric relations of the equipment to be used for treatment of the patient;
2. A computerized treatment planning system;
3. A custom block design and cutting system; and
4. Diagnostic, laboratory oncology services.

Article 2.

Criteria and Standards for Stereotactic Radiosurgery.

12 VAC 5-230-330. Availability; need for new service.

No new services should be approved unless: (i) the number of procedures performed with existing units in the planning region average more than 350 per year; and (ii) it can be reasonably projected that the proposed new service will perform at least 250 procedures in the second year of operation without reducing patient volumes to existing providers to less than 350 procedures.

12 VAC 5-230-340. Statewide Cancer Registry.

Facilities shall participate in the Statewide Cancer Registry as required by Article 9 (32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

12 VAC 5-230-350. Staffing.

The proposed new or expanded stereotactic radiosurgery services shall be under the direction of a physician who is board certified in neurosurgery and a Radiation Oncologist with training in Stereotactic Radiosurgery.

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PART IV.  
CARDIAC SERVICES.

Article 1.

Criteria and Standards for Cardiac Catheterization Services.

12 VAC 5-230-360. Accessibility.

Adult cardiac catheterization services should be accessible within 60 minutes driving time one way, under normal conditions, for 95% of the population of the planning district.

12 VAC 5-230-370. Availability.

A. No new fixed site cardiac catheterization laboratory should be approved unless:

1. All existing fixed site cardiac catheterization laboratories located in the planning district were used for at least 960 diagnostic-equivalent cardiac catheterization procedures for the relevant reporting period; and

2. It can be reasonably projected that the proposed new service will perform at least 200 diagnostic equivalent procedures in the first year of operation, 500 diagnostic equivalent procedures in the second year of operation without reducing the utilization of existing laboratories in the planning district to less than 960 diagnostic equivalent procedures at any of those existing laboratories.

B. Proposals for the use of freestanding or mobile cardiac catheterization laboratories shall be approved only if such laboratories will be provided at a site located on the campus of a general or community hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform 200 diagnostic equivalent procedures in the first year of operation, 350 diagnostic equivalent procedures in the second year of operation without reducing the utilization of existing laboratories in the planning district to less than 960 diagnostic equivalent procedures at any of those existing laboratories.

C. Consideration may be given for the approval of new cardiac catheterization services located at a general hospital located 60 minutes or more driving time one way, under normal conditions, from existing laboratories, if it can be projected that the proposed new laboratory will perform at least 200 diagnostic-equivalent procedures in the first year of operation, 400 diagnostic-equivalent procedures in the second year of operation without reducing the utilization of existing laboratories located within 60 minutes driving time one way, under normal conditions, of the proposed new service location.

D. Proposals for the addition of cardiac catheterization laboratories shall not be approved unless all existing cardiac catheterization laboratories operated in the planning district by the applicant have performed at least 1,200 diagnostic-equivalent procedures for the relevant reporting period, and the applicant can demonstrate that the expanded service will achieve a minimum of 200 diagnostic equivalent procedures per laboratory in the first 12 months of operation, 400 diagnostic equivalent procedures in the second 12 months of operation without

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reducing the utilization of existing cardiac catheterization laboratories in the planning district below 960 diagnostic equivalent procedures.

E. Emergency cardiac catheterization services shall be available within 30 minutes of admission to the facility.

F. No new or expanded pediatric cardiac catheterization services should be approved unless the proposed service will be provided at a hospital that:

1. Also provides open heart surgery services, provides pediatric tertiary care services, has a pediatric intensive care unit and provides neonatal special care; or

2. Has a cardiac intensive care unit and provides pediatric open heart surgery services;  
and

3. The applicant can demonstrate that each proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation and 200 pediatric cardiac catheterization procedures in the second year of operation.

G. Applications for new or expanded cardiac catheterization services that include non-emergent interventional cardiology services should not be approved unless emergency open heart surgery services are available within 15 minutes drive time in the hospital where the proposed cardiac catheterization service will be located.

12 VAC 5-230-380. Staffing.

A. Cardiac catheterization services should have a medical director who is board certified in cardiology and clinical experience in the performing physiologic and angiographic procedures.

In the case of pediatric cardiac catheterization services, the medical director should be board certified in pediatric cardiology and have clinical experience in performing physiologic and angiographic procedures.

B. All physicians who will be performing cardiac catheterization procedures should be board certified or board eligible in cardiology and clinical experience in performing physiologic and angiographic procedures.

In the case of pediatric catheterization services, each physician performing pediatric procedures should be board certified or board eligible in pediatric cardiology, and have clinical experience in performing physiologic and angiographic procedures.

C. All anesthesia services should be provided by, or supervised by, a board certified anesthesiologist.

In the case of pediatric catheterization services, the anesthesiologist should be experienced and trained in pediatric anesthesiology.

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Criteria and Standards for Open Heart Surgery.12 VAC 5-230-390. Accessibility

Open heart surgery services should be available 24 hours a day 7 days a week and accessible within a 60 minutes driving time one way, under normal conditions, for 95% of the population of the planning district.

12 VAC 5-230-400. Availability.A. No new open heart services should be approved unless:

1. The service will be made available in a general hospital with established cardiac catheterization services that have been used for at least 960 diagnostic equivalent procedures for the relevant reporting period and have been in operation for at least 30 months;

2. All existing open heart surgery rooms located in the planning district have been used for at least 400 open heart surgical procedures for the relevant reporting period; and

3. It can be reasonably projected that the proposed new service will perform at least 150 procedures per room in the first year of operation and 250 procedures per room in the second year of operation without reducing the utilization of existing open heart surgery programs in the planning district to less than 400 open heart procedures performed at those existing services.

B. Notwithstanding subsection A, consideration will be given to the approval of new open heart surgery services located at a general hospital more than 60 minutes driving time one way, under normal conditions, from any site in which open heart surgery services are currently available if it can be projected that the proposed new service will perform at least 150 open heart procedures in the first year of operation; and 200 procedures in the second year of operation without reducing the utilization of existing open heart surgery rooms to less than 400 procedures per room within 2 hours driving time one way, under normal conditions, from the proposed new service location.

Such hospitals should also have provided at least 960 diagnostic equivalent cardiac catheterization procedures during the relevant reporting period on equipment that has been in operation at least 30 months.

C. Proposals for the expansion of open heart surgery services should not be approved unless all existing open heart surgery rooms operated by the applicant have performed at least:

1. 400 adult-equivalent open heart surgery procedures in the relevant reporting period when the proposed facility is within two hours driving time one way, under normal conditions, of an existing open heart surgery service, or

2. 300 adult-equivalent open heart surgery procedures in the relevant reporting period when the applicant proposes expanding services in excess of two hours driving time, under normal conditions, of an existing open heart surgery service.

D. No new or expanded pediatric open heart surgery services should be approved unless the proposed new or expanded service is provided at a hospital that:

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1. Has pediatric cardiac catheterization services that have been in operation for 30 months and have performed at least 200 pediatric cardiac catheterization procedures for the relevant reporting period; and

2. Has pediatric intensive care services and provides neonatal special care.

12 VAC 5-230-410. Staffing.

A. Open heart surgery services should have a medical director certified by the American Board of Thoracic Surgery in cardiovascular surgery with special qualifications and experience in cardiac surgery.

In the case of pediatric open heart surgery, the medical director shall be certified by the American Board of Thoracic Surgery in cardiovascular surgery and experience in pediatric cardiovascular surgery and congenital heart disease.

B. All physicians performing open heart surgery procedures should be board certified or board eligible in cardiovascular surgery, with experience in cardiac surgery. In addition to the cardiovascular surgeon who performs the procedure, there should be a suitably trained board certified or board eligible cardiovascular surgeon acting as an assistant during the open heart surgical procedure. There should also be present at least one board certified or board eligible anesthesiologist with experience in open heart surgery.

In the case of pediatric open heart surgery services, each physician performing and assisting with pediatric procedures should be board certified or board eligible in cardiovascular surgery with experience in pediatric cardiovascular surgery. In addition to the cardiovascular surgeon who performs the procedure, there should be a suitably trained board certified or board eligible cardiovascular surgeon acting as an assistant during the open heart surgical procedure. All pediatric procedures should include a board certified anesthesiologist with experience in pediatric anesthesiology and pediatric open heart surgery.

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PART V.  
GENERAL SURGICAL SERVICES.

12 VAC 5-230-420. Accessibility.

Surgical services should be available within 30 minutes driving time one way, under normal conditions, for 95% of the population of the planning district.

12 VAC 5-230-430. Availability.

A. The combined number of inpatient and outpatient general purpose surgical operating rooms needed in a planning district, exclusive of Level I and Level II Trauma Centers dedicated to the needs of the trauma service, dedicated cesarean section rooms, or operating rooms designated exclusively for open heart surgery, will be determined as follows:

$$\text{FOR} = \frac{((\text{ORV}/\text{POP}) \times (\text{PROPOP})) \times \text{AHORV}}{1600}$$

ORV = the sum of total operating room visits (inpatient and outpatient) in the planning district in the most recent five years for which operating room utilization data has been reported by Virginia Health Information; and

POP = the sum of total population in the planning district in the most recent five years for which operating room utilization data has been reported by Virginia Health Information, as found in the most current projections of the Virginia Employment Commission.

PROPOP = the projected population of the planning district five years from the current year as reported in the most current projections of the Virginia Employment Commission.

AHORV = the average hours per general purpose operating room visit in the planning district for the most recent year for which average hours per general purpose operating room visit has been calculated from information collected by Virginia Health Information.

FOR = future general purpose operating rooms needed in the planning district five years from the current year.

1600 = available service hours per operating room per year based on 80% utilization of an operating room that is available 40 hours per week, 50 weeks per year.

B. Projects involving the relocation of existing general purpose operating rooms within a planning district may be authorized when it can be reasonably documented that such relocation will: (i) improve the distribution of surgical services within a planning district by making services available within 30 minutes driving time one way, under normal conditions, of 95% of the planning district's population.

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PART VI.  
GENERAL INPATIENT SERVICES.

12 VAC 5-230-440. Accessibility.

Acute care inpatient facility beds should be within 30 minutes driving time one way, under normal conditions, of 95% of the population of a planning district.

12 VAC 5-230-450. Availability.

A. Subject to the provisions of 12 VAC 5-230-80, no new inpatient beds should be approved in any planning district unless:

1. The resulting number of beds does not exceed the number of beds projected to be needed, for each inpatient bed category, for that planning district for the fifth planning horizon year;

2. The average annual occupancy, based on the number of beds, is at least 70 % (midnight census) for the relevant reporting period; or

3. The intensive care bed capacity has an average annual occupancy of at least 65% for the relevant reporting period, based on the number of beds.

B. No proposal to replace or relocate inpatient beds to a location not contiguous to the existing site should be approved unless:

1. Off-site replacement is necessary to correct life safety or building code deficiencies;

2. The population currently served by the beds to be moved will have reasonable access to the beds at the new site, or to neighboring inpatient facilities;

3. The beds to be replaced experienced an average annual utilization of 70% (midnight census) for general inpatient beds and 65% for intensive care beds in the relevant reporting period;

4. The number of beds to be moved off-site is taken out of service at the existing facility;  
and

5. The off-site replacement of beds results in: (i) a decrease in the licensed bed capacity, (ii) a substantial cost savings, cost avoidance, or consolidation of underutilized facilities, or (iii) generally improved operating efficiency in the applicant's facility or facilities.

C. For proposals involving a capital expenditure of \$ 5 million or more, and involving the conversion of under-utilized beds to medical/surgical, pediatric or intensive care, consideration will be given to a proposal if: (i) there is a projected need in the category of inpatient beds that would result from the conversion; and (ii) it can be demonstrated that the average annual occupancy of the beds to be converted would reach the standard in subdivision B.1-3 for the bed category that would result from the conversion, by the first year of operation.

D. In addition to the terms of 12 VAC 5-230-80, a need for additional general inpatient beds may be demonstrated if the total number of beds in a given category in the planning district is less than the number of such beds projected as necessary to meet demand in the fifth planning

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horizon year for which the application is submitted.

E. The number of medical/surgical beds projected to be needed in a planning district shall be computed as follows:

1. Determine the projected total number of medical/surgical and pediatric inpatient days for the fifth planning horizon year as follows:

a. Add the medical/surgical and pediatric inpatient days for the past three years for all acute care inpatient facilities in the planning district as reported in the Annual Survey of Hospitals;

b. Add the projected planning district population for the same three year period as reported by the Virginia Employment Commission;

c. Divide the total of the medical/surgical and pediatric inpatient days by the total of the population and express the resulting rate in days per 1,000 population;

d. Multiply the days per 1,000 population rate by the projected population for the planning district (expressed in 1,000s) for the fifth planning horizon year.

2. Determine the projected number of medical/surgical and pediatric beds that may be needed in the planning district for the planning horizon year as follows:

a. Divide the result in subdivision E.1.d. by 365;

b. Divide the quotient obtained by 0.80 in planning districts in which fifty percent or more of the population resides in non-rural areas or 0.75 in planning districts in which less than fifty percent of the population resides in non-rural areas.

3. Determine the projected number of medical/surgical and pediatric beds that may be established or relocated within the planning district for the fifth planning horizon year as follows:

a. Determine the number of medical/surgical and pediatric beds as reported in the inventory;

b. Subtract the number of beds identified in subdivision E.1 from the number of beds needed as determined in subdivision E.2.b. If the difference indicated is positive, then a need may exist for additional medical/surgical or pediatric beds. If the difference is negative, then no need for additional beds exists.

F. The projected need for intensive care beds shall be computed as follows:

1. Determine the projected total number of intensive care inpatient days for the fifth planning horizon year as follows:

a. Add the intensive care inpatient days for the past three years for all inpatient facilities in the planning district as reported in the annual survey of hospitals;

b. Add the planning district's projected population for the same three-year period as reported by the Virginia Employment Commission;

c. Divide the total of the intensive care days by the total of the population to obtain the rate in days per 1,000 population;

d. Multiply the days per 1,000 population rate by the projected population for the planning district (expressed in 1,000s) for the fifth planning horizon year to yield the expected

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intensive care patient days.

2. Determine the projected number of intensive care beds that may be needed in the planning district for the planning horizon year as follows:

a. Divide the number of days projected in subdivision F.1.d. by 365 to yield the projected average daily census;

b. Calculate the beds needed to assure with 99% probability that an intensive care bed will be available for unscheduled admissions;

3. Determine the projected number of intensive care beds that may be established or relocated within the planning district for the fifth planning horizon year as follows:

a. Determine the number of intensive care beds as reported in the inventory.

b. Subtract the number of beds identified in subdivision F.3.a from the number of beds needed as determined in subdivision F.2.b. If the difference is positive, then a need may exist for additional intensive care beds. If the difference is negative, then no need for additional beds exists.

G. No hospital should relocate beds to a new location if underutilized beds (less than 85% average annual occupancy for medical/surgical and pediatric beds), when the relocation involves such beds, and less than 65% average annual occupancy for intensive care beds when relocation involves such beds are available within 30 minutes of the site of the proposed hospital.

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PART VII.  
NURSING FACILITIES.

12 VAC 5-230-460. Accessibility.

A. Nursing facility beds should be accessible within 60 minutes driving time one way, under normal conditions, to 95% of the population in a planning region.

B. Nursing facilities should be accessible by public transportation when such systems exist in an area.

C. Preference will be given to proposals that improve geographic access and reduce travel time to nursing facilities within a planning district.

12 VAC 5-230-470. Availability.

A. No planning district shall be considered to have a need for additional nursing facility beds unless: (i) the bed need forecast in that planning district (see subdivision D) exceeds the current inventory of beds in that planning district; and (ii) the estimated average annual occupancy of all existing Medicaid-certified nursing facility beds in the planning district was at least 93% for the most recent two years following the first year of operation of new beds, excluding the bed inventory and utilization of the Virginia Veterans Care Center.

B. No planning district shall be considered to have a need for additional beds if there are unconstructed beds designated as Medicaid-certified.

C. Proposals for expanding existing nursing facilities should not be approved unless the facility has operated for at least two years and the average annual occupancy of the facility's existing beds was at least 93% in the most recent year for which bed utilization has been reported to the department.

Exceptions will be considered for facilities that operated at less than 93% average annual occupancy in the most recent year for which bed utilization has been reported when the facility has a rehabilitative or other specialized care focus that results in a relatively short average length of stay, causing an average annual occupancy lower than 93% for the facility.

D. The bed need forecast will be computed as follows:

$$\text{PDBN} = (\text{UR64} \times \text{PP64}) + (\text{UR69} \times \text{PP69}) + (\text{UR74} \times \text{PP74}) + (\text{UR79} \times \text{PP79}) + (\text{UR84} \times \text{PP84}) + (\text{UR85} \times \text{PP85}) \text{ where:}$$

PDBN = Planning district bed need.

UR64 = The nursing home bed use rate of the population aged 0 to 64 in the planning district as determined in the most recent nursing home patient origin study authorized by the department.

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PP64 = The population aged 0 to 64 projected for the planning district three years from the current year as most recently published by the Virginia Employment Commission.

UR69 = The nursing home bed use rate of the population aged 65 to 69 in the planning district as determined in the most recent nursing home patient origin study authorized by the department.

PP69 = The population aged 65 to 69 projected for the planning district three years from the current year as most recently published by the Virginia Employment Commission.

UR74 = The nursing home bed use rate of the population aged 70 to 74 in the planning district as determined in the most recent nursing home patient origin study authorized by the department.

PP74 = The population aged 70 to 74 projected for the planning district three years from the current year as most recently published by the Virginia Employment Commission.

UR79 = The nursing home bed use rate of the population aged 75 to 79 in the planning district as determined in the most recent nursing home patient origin study authorized by the department.

PP79 = The population aged 75 to 79 projected for the planning district three years from the current year as most recently published by the Virginia Employment Commission.

UR84 = The nursing home bed use rate of the population aged 80 to 84 in the planning district as determined in the most recent nursing home patient origin study authorized by the department.

PP84 = The population aged 80 to 84 projected for the planning district three years from the current year as most recently published by the Virginia Employment Commission.

UR85+ = The nursing home bed use rate of the population aged 85 and older in the planning district as determined in the most recent nursing home patient origin study authorized by the department.

PP85+ = The population aged 85 and older projected for the planning district three years from the current year as most recently published by the Virginia Employment Commission.

Planning district bed need forecasts will be rounded as follows:

<u>Planning District Bed Need</u>	<u>Rounded Bed Need</u>
<u>1 – 29</u>	<u>0</u>
<u>30 – 44</u>	<u>30</u>
<u>45 – 84</u>	<u>60</u>
<u>85 – 104</u>	<u>90</u>
<u>105 – 134</u>	<u>120</u>
<u>135 – 164</u>	<u>150</u>
<u>165 – 194</u>	<u>180</u>

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<u>195 – 224</u>	<u>210</u>
<u>225+</u>	<u>240</u>

except in the case of a planning district that has two or more nursing facilities, has had an average annual occupancy rate in excess of 93% for the most recent two years for which bed utilization has been reported to the department, and has a forecasted bed need of 15 to 29 beds. In such a case, the bed need for this planning district will be rounded to 30.

E. No new freestanding nursing facilities of less than 90 beds should be authorized. Consideration will be given to new freestanding facilities with fewer than 90 nursing facility beds when such facilities can be justified on the basis of a lack of local demand for a larger facility and a maldistribution of nursing facility beds within a planning district.

F. Proposals for the development of new nursing facilities or the expansion of existing facilities by continuing care retirement communities will be considered when:

1. The total number of new or additional beds plus any existing nursing facility beds operated by the continuing care provider does not exceed 10% of the continuing care provider's total existing or planned independent living and adult care residence;

2. The proposed beds are necessary to meet existing or reasonably anticipated obligations to provide care to present or prospective residents of the continuing care facility;

3. The applicant agrees in writing not to seek certification for the use of such new or additional beds by persons eligible to receive Medicaid;

4. The applicant agrees in writing to obtain the resident's written acknowledgement, prior to admission, that the applicant does not serve Medicaid recipients and that, in the event such resident becomes a Medicaid recipient and is eligible for nursing facility placement, the resident will not be eligible for placement in the CCRC's nursing facility unit;

5. The applicant agrees in writing that only continuing care contract holders who have resided in the CCRC as independent living residents or adult care residents will be admitted to the nursing facility unit after the first three years of operation.

H. The construction cost of proposed nursing facilities should be comparable to the most recent cost for similar facilities in the same health planning region. Consideration should be given to the current capital cost reimbursement methodology utilized by the Department of Medical Assistance Services.

I. Consideration should be given to applicants proposing to replace outdated and functionally obsolete facilities with modern nursing facilities that will result in the more cost efficient delivery of health care services to residents in a more aesthetically pleasing and comfortable environment. Proponents of the replacement and relocation of nursing facility beds should demonstrate that the replacement and relocation are reasonable and could result in savings in other cost centers, such as realized operational economies of scale and lower maintenance costs.

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PART VIII.  
Lithotripsy Services.

12 VAC 5-230-480. Accessibility.

A. The waiting time for lithotripsy services should be no more than one week.

B. Lithotripsy services should be available within 30 minutes driving time in urban areas and 45 minutes driving time one way, under normal conditions, for 95% of the population of the health planning region.

12 VAC 5-230-490. Availability.

A. Consideration will be given to new lithotripsy services established at a general hospital through contract with, or by lease of equipment from, an existing service provider authorized to operate in Virginia, provided the hospital has referred at least two patients per week, or 100 patients annually, for the relevant reporting period to other facilities for lithotripsy services.

B. A new service may be approved at the site of any general hospital or hospital-based clinic or licensed outpatient surgical hospital provided the service is provided by:

1. A vendor currently providing services in Virginia;
2. A vendor not currently providing services can demonstrate that the proposed unit can provide at least 750 procedures annually at all sites served; or
3. The applicant can demonstrate that the proposed unit can provide at least 750 procedures annually at all sites to be served.

C. Proposals for the expansion of services by existing vendors or providers of such services may be approved if it can be demonstrated that each existing unit owned or operated by that vendor or provider has provided a minimum of 750 procedures annually at all sites served by the vendor or provider.

D. A new or expanded lithotripsy service may be approved when the applicant is a consortium of hospitals or a hospital network, when a majority of procedures will be provided at sites or facilities owned or operated by the hospital consortium or by the hospital network .

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PART IX.  
ORGAN TRANSPLANT.

12 VAC 5-230-500. Accessibility.

A. Organ transplantation services should be accessible within two hours driving time one way, under normal conditions, of 95% of Virginia's population.

B. Providers of organ transplantation services should facilitate access to pre- and post-transplantation services needed by patients residing in rural locations by establishing part-time satellite clinics.

12 VAC 5-230-510. Availability.

A. There should be no more than one program for each transplantable organ in a health planning region.

B. Proposals to expand existing transplantation programs shall demonstrate that existing organ transplantation services comply with all applicable Medicare program coverage criteria.

12 VAC 5-230-520. Minimum utilization; minimum survival rate; service proficiency; systems operations.

A. Proposals to establish or expand organ transplantation services should demonstrate that the minimum number of transplants would be performed annually. The minimum number transplants required by organ system is:

<u>Kidney</u>	<u>30</u>
<u>Pancreas or</u>	
<u>kidney/pancreas</u>	<u>12</u>
<u>Heart</u>	<u>17</u>
<u>Heart/Lung</u>	<u>12</u>
<u>Lung</u>	<u>12</u>
<u>Liver</u>	<u>21</u>
<u>Intestine</u>	<u>2</u>

Performance of minimum transplantation volumes does not indicate a need for additional transplantation capacity or programs.

B. Preference will be given to expansion of successful existing services, either by enabling necessary increases in the number of organ systems being transplanted or by adding transplantation capability for additional organ systems, rather than developing additional programs that could reduce average program volume.

C. Facilities should demonstrate that they will achieve and maintain minimum transplant

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patient survival rates. Minimum one-year survival rates, listed by organ system, are:

<u>Kidney</u>	<u>95%</u>
<u>Pancreas or kidney/pancreas</u>	<u>90%</u>
<u>Heart</u>	<u>85%</u>
<u>Heart/Lung</u>	<u>60%</u>
<u>Lung</u>	<u>77%</u>
<u>Liver</u>	<u>86%</u>
<u>Intestine</u>	<u>77%</u>

D. Proposals to add additional organ transplantation services should demonstrate at least two years successful experience with all existing organ transplantation systems.

E. All physicians that perform transplants should be board certified by the appropriate professional examining board, and should have a minimum of one year of formal training and two years of experience in transplant surgery and post-operative care.

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PART X.  
MISCELLANEOUS CAPITAL EXPENDITURES.

12 VAC 5-230-530. Purpose.

This part of the SMFP is intended to provide general guidance in the review of projects that require COPN authorization by virtue of their expense but do not involve changes in the bed or service capacity of a medical care facility addressed elsewhere in this chapter. This part may be used in coordination with other Parts of the SMFP addressing changes in bed or service capacity used in the COPN review process.

12 VAC 5-230-540. Project need.

All applications involving the expenditure of \$5 million dollars or more by a medical care facility should include documentation that the expenditure is necessary in order for the facility to meet the identified medical care needs of the public it serves. Such documentation should clearly identify that the expenditure:

1. Represents the most cost-effective approach to meeting the identified need; and
2. The ongoing operational costs will not result in unreasonable increases in the cost of delivering the services provided.

12 VAC 5-230-550. Facilities expansion.

Applications for the expansion of medical care facilities should document that the current space provided in the facility for the areas or departments proposed for expansion are inadequate. Such documentation should include:

1. An analysis of the historical volume of work activity or other activity performed in the area or department;
2. The projected volume of work activity or other activity to be performed in the area or department; and
3. Evidence that contemporary design guidelines for space in the relevant areas or departments, based on levels of work activity or other activity, are consistent with the proposal.

12 VAC 5-230-560. Renovation or modernization.

A. Applications for the renovation or modernization of medical care facilities should provide documentation that:

1. The timing of the renovation or modernization expenditure is appropriate within the life cycle of the affected building or buildings; and
2. The benefits of the proposed renovation or modernization will exceed the costs of the renovation or modernization over the life cycle of the affected building or buildings to be renovated or modernized.

B. Such documentation should include a history of the affected building or buildings.

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including a chronology of major renovation and modernization expenses.

C. Applications for the general renovation or modernization of medical care facilities should include downsizing of beds or other service capacity when such capacity has not operated at a reasonable level of efficiency as identified in the relevant sections of this chapter, during the most recent three year period.

12 VAC 5-230-570. Equipment.

Applications for the purchase and installation of equipment by medical care facilities that are not addressed elsewhere in this chapter should document that the equipment is needed. Such documentation should clearly indicate that the: (i) proposed equipment is needed to maintain the current level of service provided; or (ii) benefits of the change in service resulting from the new equipment exceed the costs of purchasing or leasing and operating the equipment over its useful life.

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PART XI.  
MEDICAL REHABILITATION.

12 VAC 5-230-580. Accessibility.

Comprehensive inpatient rehabilitation services should be available within 60 minutes driving time one way, under normal conditions, of 95% of the population of the planning region.

12 VAC 5-230-590. Availability.

A. The number of comprehensive and specialized rehabilitation beds needed in a health planning region will be projected as follows:

$$\frac{[(UR \times PROJ. POP.)/365]}{.90}$$

Where UR = the use rate expressed as rehabilitation patient days per population in the health planning region as reported in the most recent "Industry Report for Virginia Hospitals and Nursing Facilities" published by Virginia Health Information; and

PROJ.POP. = the most recent projected population of the health planning region three years from the current year as published by the Virginia Employment Commission.

B. No additional rehabilitation beds should be authorized for a health planning region in which existing rehabilitation beds were utilized at an average annual occupancy of less than 90% in the most recently reported year.

Preference will be given to the development of needed rehabilitation beds through the conversion of underutilized medical/surgical beds.

C. Notwithstanding subsection A, the need for proposed inpatient rehabilitation beds will be given consideration when:

1. The rehabilitation specialty proposed is not currently offered in the health planning region; and

2. A documented basis for recognizing a need for the service or beds is provided by the applicant.

12 VAC 5-230-600. Staffing.

Medical rehabilitation facilities should have full-time medical direction by a psychiatrist or other physician with a minimum of two years experience in the proposed specialized inpatient medical rehabilitation program.

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PART XII.  
MENTAL HEALTH SERVICES.

Article 1.  
Psychiatric and Substance Abuse Disorder Treatment Services

12 VAC 5-230-610. Accessibility.

A. Acute psychiatric, acute substance abuse disorder treatment services, and intermediate care substance abuse disorder treatment services should be available within 60 minutes driving time one way, under normal conditions, of 95% of the population.

B. Existing and proposed acute psychiatric, acute substance abuse disorder treatment, and intermediate care substance abuse disorder treatment service providers shall have established plans for the provision of services to indigent patients which include, at a minimum: (i) the minimum number of un-reimbursed patient days to be provided to indigent patients who are not Medicaid recipients; (ii) the minimum number of Medicaid-reimbursed patient days to be provided, unless the existing or proposed facility is ineligible for Medicaid participation; (iii) the minimum number of un-reimbursed patient days to be provided to local community services boards; and (iv) a description of the methods to be utilized in implementing the indigent patient service plan and assuring the provision of the projected levels of un-reimbursed and Medicaid-reimbursed patient days.

C. Proposed acute psychiatric, acute substance abuse disorder treatment, and intermediate care substance abuse disorder treatment service providers shall have formal agreements with their identified community services boards that: (i) specify the number of charity care patient days which will be provided to the community service board; (ii) describe the mechanisms to monitor compliance with charity care provisions; (iii) provide for effective discharge planning for all patients, including return to the patients place of origin or home state if not Virginia); and (iv) consider admission priorities based on relative medical necessity.

D. Providers of acute psychiatric, acute substance abuse disorder treatment, and intermediate care substance abuse disorder treatment services serving large geographic areas should establish satellite outpatient facilities to improve patient access, where appropriate and feasible.

12 VAC 5-230-620. Availability.

A. The combined number of acute psychiatric and acute substance abuse disorder treatment beds needed in a planning district with existing acute psychiatric or acute substance abuse disorder treatment beds or both will be determined as follows:

$$\frac{[(UR \times PROJ.POP.)/365]}{.75}$$

Where UR = the use rate of the planning district expressed as the average acute psychiatric and

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acute substance abuse disorder treatment patient days per population reported for the most recent 5 year period; and

PROJ.POP. = the projected population of the planning district 5 years from the current year as reported in the most recent published projections of the Virginia Employment Commission.

For purposes of this methodology, no beds shall be included in the inventory of psychiatric or substance abuse disorder beds when these beds (i) are in facilities operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services; (ii) have been converted to other uses; (iii) have been vacant for six months or more; or (iv) are not currently staffed and cannot be staffed for acute psychiatric or substance abuse disorder patient admissions within 24 hours.

B. Subject to the provisions of 12 VAC 5-230-80, no additional acute psychiatric or acute substance abuse disorder treatment beds should be authorized for a planning district with existing acute psychiatric or acute substance abuse disorder treatment beds or both if the existing inventory of such beds is greater than the need identified using the above methodology.

However, consideration will be given to the addition of acute psychiatric or acute substance abuse disorder beds by existing medical care facilities in planning districts with an excess supply of beds when such additions can be justified on the basis of facility-specific utilization or geographic remoteness, i.e., driving time of 60 minutes or more, one way under normal conditions, to alternate acute care facilities. If the facility with the institutional need for beds is part of a hospital network, underutilized beds at the other facilities within the network should be relocated to the facility with the institutional need if possible.

C. No existing acute psychiatric or acute substance disorder abuse treatment beds should be relocated unless it can be reasonably projected that the relocation will not have a negative impact on the ability of existing acute psychiatric or substance abuse disorder treatment providers or both to continue to provide historic levels of service to Medicaid or other indigent patients.

D. The combined number of acute psychiatric and acute substance abuse disorder treatment beds needed in a planning district without existing acute psychiatric or acute substance abuse disorder treatment beds will be determined as follows:

$$\frac{[(UR \times PROJ.POP.)/365]}{.80}$$

Where UR = the use rate of the health planning region in which the planning district is located expressed as the average acute psychiatric and acute substance abuse disorder treatment patient days per population reported for the most recent 3 5 year period;

PROJ.POP. = the projected population of the planning district 3 5 years from the current year as reported in the most recent published projections of the Virginia Employment Commission.

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E. Preference will be given to the development of needed acute psychiatric and intermediate substance abuse disorder treatment beds through the conversion of unused general hospital beds. Preference will also be given to proposals for acute psychiatric and substance abuse beds demonstrating a willingness to accept persons under temporary detention orders (TDO) and have contractual agreements to serve populations served by Community Services Boards, whether through conversion of under-utilized general hospital beds or development of new beds.

F. The number of intermediate care substance disorder abuse treatment beds needed in a planning district with existing intermediate care substance abuse disorder treatment beds will be determined as follows:

$$\frac{[(UR \times PROJ.POP.)/365]}{.75}$$

Where UR = the use rate of the planning district expressed as the average intermediate care substance abuse disorder treatment patient days per population reported for the most recent three year period; and

PROJ.POP. = the projected population of the planning district three years from the current year as reported in the most recent published projections of the Virginia Employment Commission.

G. Subject to the provisions of 12 VAC 5-230-80, no additional intermediate care substance abuse disorder treatment beds should be authorized for a planning district with existing intermediate care substance abuse disorder treatment beds if the existing inventory of such beds is greater than the need identified. No beds in facilities operated by DMHMRSAS will be included in the inventory of intermediate care substance abuse disorder beds.

However, consideration will be given to the addition of intermediate care substance abuse disorder treatment beds by existing medical care facilities in planning districts with an excess supply of beds when such addition can be justified on the basis of facility-specific utilization or geographic remoteness, i.e., driving time of 60 minutes or more one way under normal conditions, to alternate acute care facilities. If the facility with the institutional need for beds is part of a hospital network, underutilized beds at the other facilities within the network should be relocated to the facility with the institutional need if possible.

H. No existing intermediate care substance abuse disorder treatment beds should be relocated from one site to another unless it can be reasonably projected that the relocation will not have a negative impact on the ability of existing intermediate care substance abuse disorder treatment providers to continue to provide historic levels of service to indigent patients.

I. The number of intermediate care substance abuse disorder treatment beds needed in a planning district without existing intermediate care substance abuse disorder treatment beds will be determined as follows:

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$$\frac{[(UR \times PROJ.POP.)/365]}{.75}$$

Where UR = the use rate of the health planning region in which the planning district is located expressed as the average intermediate care substance abuse disorder treatment patient days per population reported for the most recent three year period;

PROJ.POP. = the projected population of the planning district three years from the current year as reported in the most recent published projections of the Virginia Employment Commission.

J. Preference will be given to the development of needed intermediate care substance abuse disorder treatment beds through the conversion of under-utilized general hospital beds.

Article 2.  
Mental Retardation.

12 VAC 5-230-630. Availability.

The establishment of new ICF/MR facilities should not be authorized unless the following conditions are met:

1. Alternatives to the proposed service are not available in the area to be served by the new facility;
2. There is a documented source of referrals for the proposed new facility;
3. The manner in which the proposed new facility fits into the continuum of care for the mentally retarded is identified;
4. There are distinct and unique geographic, socioeconomic, cultural, transportation, or other factors affecting access to care that require development of a new ICF/MR;
5. Alternatives to the development of a new ICF/MR consistent with the Medicaid waiver program have been considered and can be reasonably discounted in evaluating the need for the new facility.
6. The proposed new facility is consistent with the current DMHMRSAS Comprehensive Plan and the mental retardation service priorities for the catchment area identified in the plan;
7. Ancillary and supportive services needed for the new facility are available; and
8. Service alternatives for residents of the proposed new facility who are ready for discharge from the ICF/MR setting are available.

12 VAC 5-230-640. Continuity; integration.

Each facility should have a written transfer agreement with one or more hospitals for the transfer of emergency cases if such hospitalization becomes necessary.

12 VAC 5-230-650. Acceptability.

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Mental retardation facilities should meet all applicable licensure standards as specified in 12 VAC 35-105, Rules and Regulations of the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services.

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PART XIII.  
PERINATAL SERVICES.

Article 1.  
Criteria and Standards for Obstetrical Services.

12 VAC 5-230-670. Accessibility.

Obstetrical services should be located within 30 minutes driving time one way, under normal conditions, of 95% of the population in rural areas and within 30 minutes driving time one way, under normal conditions, in urban and suburban areas.

12 VAC 5-230-680. Availability.

A. Proposals to establish new obstetrical services in rural areas should demonstrate that obstetrical volumes within the travel times listed in 12 VAC 5-230-670 will not be negatively affected.

B. Proposals to establish new obstetrical services in urban and suburban areas should demonstrate that a minimum of 2,500 deliveries will be performed annually by the second year of operation and that obstetrical volumes of existing providers located within the travel times listed in 12 VAC 5-230-670 will not be negatively affected.

C. Applications to improve existing obstetrical services, and to reduce costs through consolidation of two obstetrical services into a larger, more efficient service will be given preference over the addition of new services or the expansion of single service providers.

12 VAC 5-230-690. Continuity.

A. Perinatal service capacity should be developed and sized to provide routine newborn care to infants delivered in the associated obstetrics service, and shall have the capability to stabilize and prepare for transport those infants requiring the care of a neonatal special care services unit.

B. The application should identify the primary and secondary neonatal special care center nearest the proposed service and provide travel time one-way, under normal conditions, to those centers.

Article 2.  
Neonatal Special Care Services.

12 VAC 5-230-700. Accessibility.

Neonatal special care services should be located within an average of 45 minutes driving time one way, under normal conditions, in urban and suburban areas of hospitals providing

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general level newborn services.

12 VAC 5-230-710. Availability.

A. Existing neonatal special care units located within the travel times listed in 12 VAC 5-230-670 should achieve 65% average annual occupancy before new services can be added to the planning region.

B. Preference will be given to the expansion of existing services, rather than the creation of new services.

12 VAC 5-230-720. Neonatal services.

The application should identify the service area, levels of service, and capacity of the current general level newborn service hospitals to be served within the identified area.

I certify that this regulation is full, true, and correctly dated.

\_\_\_\_\_  
Robert B. Stroube, M.D., M.P.H.  
State Health Commissioner

\_\_\_\_\_  
Date